Short Communication

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# Update on PV in the Balkans

## Abstract

Objectives of pharmacovigilance are promoting the rational, safe and effective use of medicines, preventing harm from adverse reactions, minimising risks and contributing to the protection of patients and public health. The main emphasis of this article is on pharmacovigilance regulation. Countries of interest are North Macedonia, Serbia, Bosnia & Herzegovina, Montenegro, Albania and Kosovo. Readers will get an indepth look at regulation compliance from the emerging markets within country-specific environments.

**Keywords:** safety, pharmacovigilance, medicines, regulation, Balkan countries

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## Introduction

Medicinal products are characterized by its efficacy, quality and safety. Pharmaceutical industry is highly regulated, with even more stringent requirements coming every day, one of which and of great importance is pharmacovigilance. Local Qualified Person for Pharmacovigilance (QPPV) should have good knowledge in PV and Quality Management System, English language, have regular trainings and audits. They should actively follow the local regulation, but also the regulation from countries where the companies are distributing their medicinal products.

## Countries of interest

These are the countries where the small generic company Bionika Pharmaceuticals is most active, mainly in the neighbouring countries: Serbia, Montenegro, Bosnia & Herzegovina, Albania and Kosovo. Bionika Pharmaceuticals is manufacturing medicinal products, medical devices, food supplements & medical cosmetics and is located in North Macedonia, in the Balkan Peninsula, Southeast Europe. All countries follow the EU regulation for medicinal products.

## Discussion

### North Macedonia

In Macedonia local QPPV and responsible person for regulatory affairs (RA) can be the same person. Despite electronic submission of Individual Case Safety Reports (ICSRs), XML E2B(R3) format is preferred; paper format is only accepted in exceptional cases. E2B(R2) can be converted to E2B(R3) in the system and vice versa (Figure 1). Serious ICSRs from the country should be submitted within 15 days and non-serious ICSRs within 90 days; serious and unexpected non-serious ICSRs only from outside the country. ICSRs can be submitted both by healthcare professionals (HCPs) & patients. Marketing Authorisation Holder (MAH) is always local company from the country (Figure 1).[1]

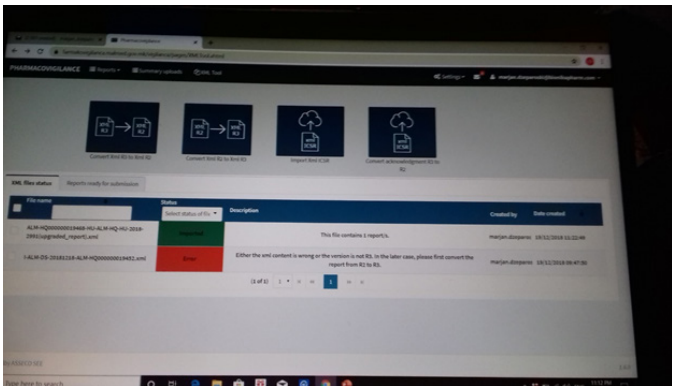

**Figure 1** MALMED – view of agency e-portal system.

### Serbia

In Serbia is required separate dedicated local QPPV. Paper ICSRs are accepted rarely, preferred is electronic submission of ICSRs, specially after the start of COVID-19 pandemic. Serious ICSRs from the country should be submitted within 15 days and non-serious ICSRs within 90 days; only serious, unexpected ICSRs from outside the country within 15 days, except ICSRs already submitted in EudraVigilance and Upsala Monitoring Centre. ICSRs can be submitted both by HCPs & patients. RMP submission is obligatory. Marketing Authorisation Holder (MAH) is always local company from the country.[2]

### Montenegro

For PV & RA can be the same responsible person. Both is possible, paper & electronic submission of ICSRs.

Serious ICSRs from the country should be submitted within 15 days and non-serious ICSRs within 90 days; at the request of Agency only serious and unexpected ICSRs from outside the country are submitted within 15 days. ICSRs can be submitted by HCPs & patients. RMP submission is obligatory.[3] Local MAH (*MAH can be from EU after EU accession /Law on medicines *("Official Gazette of Montenegro", No. 80/20)*).

### Bosnia & Herzegovina

Separate dedicated local QPPV is required. Both is possible, paper & electronic submission (from 03.2019) of ICSRs. Serious and unexpected ICSRs from the country and from outside should be submitted within 15 days. ICSRs can be submitted both by HCPs & patients (only for medical devices). PSUR submission through e-portal (01.01.2020)/test phase, from 01.04.2020 it is mandatory. RMP submission: obligatory from 19.08.2021. Local MAH.[4] PSUR submission timelines (after obtaining Marketing Authorization): 1st year on 6 months, following 2 years once/year, after that once/year every 3 years (all countries).

### Kosovo*

Separate dedicated local QPPV is required. Electronic submission/mail of ICSRs only (from 11.2019). All serious ICSRs from the country and from outside should be submitted within 15 days and non-serious ICSRs within 90 days. ICSRs can be submitted only by HCPs.[5]

### Albania*

For PV & RA can be the same responsible person. Electronic submission of ICSRs: e-mail or on the following web-page http://akbpm.gov.al/formulate-raportimi (Albanian language only). Serious ICSRs from the country should be submitted within 15 days and non-serious ICSRs within 90 days; serious ICSRs only from outside the country (within 15 days), for non-serious ICSRs submission is optional, not obligatory. ICSRs can be submitted both by HCPs & patients.[6]

From all countries of interest, the following is valid only for both countries:

*Marketing Authorisation Holder is either the manufacturer or the foreign MAH.

## Conclusion

All countries are following EU Regulation, but there are differences in-between countries. North Macedonia is the only country from the region which has developed own data processing network and management system for ICSRs submission. Trainings and education/continuous learning are needed for the QPPVs; audits are essential.

It is expected that all countries will develop similar network and management system in the near future. On that way the regional aspects are moving towards global aspects and harmonization can be achieved in the near future.

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## Conflicts of interest

Author declares that there is no conflict of interest.

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